UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

VICTORIA LYNN WILLIAMS *Plaintiff* VS. DEROYAL INDUSTRIES, INC. *Defendant*	§ § § § § § § § §	CIVIL ACTION 3:11-cv-166 JURY REQUESTED

PLAINTIFF'S ORIGINAL COMPLAINT
AND DEMAND FOR JURY TRIAL

COMES NOW Victoria Lynn Williams, Plaintiff, complaining of DeRoyal Industries, Inc., Defendant. This action is brought on behalf of Plaintiff who suffered damages as a direct and proximate result of Defendant's negligent and wrongful misconduct in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, and sale of the DeRoyal T600 (hereinafter referred to as "CTU" or "the subject product").

I.
PARTIES

1.1 Plaintiff is a citizen and resident of Angleton, Brazoria County, Texas. She is bringing her individual claims for her injuries.

1.2 Defendant is a Tennessee corporation with its principal place of business in Tennessee. It may be served with process through its registered agent for service of process, Autry O. DeBusk, 200 DeBusk Lane, Powell, Tennessee 37849.

II.
JURISDICTION AND VENUE

2.1 This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a), because this action, which has an amount in controversy in excess of $75,000, is between citizens of different states. Plaintiff is a resident and citizen of the Texas, and Defendant is a resident and citizen of Tennessee.

2.2 This Court has personal jurisdiction over Defendant because Defendant does business in Texas and has sufficient contacts with Texas, both generally and with regard to this specific action, so that the exercise of personal jurisdiction over it is proper.

2.3 Venue is proper in the Southern District of Texas – Galveston Division, pursuant to 28 U.S.C. §1391(a)(2), because this is the District in which a substantial part of the events or omissions giving rise to the claim occurred. More specifically, the subject product was used by Plaintiff in this District, and Plaintiff's resulting injuries and damages occurred in this District.

III.
FACTUAL ALLEGATIONS

3.1 Ice bags, as an example, are used and have been used as a means of healing at the site of an injury by, *inter alia*, reducing swelling and pain. Manufacturers such as Defendant perceived a problem – i.e., the ice melted reducing the duration of the cold therapy. To solve this perceived problem, manufacturers such as Defendant insulated the ice in an ice-chest and circulated cold water in the ice through a hose to a pad that would be wrapped around the injury site requiring cold therapy. In short, the aforementioned design implemented in the CTU increased the durations (i.e., time) and decreased the temperatures in the "new form of cold therapy" relative to traditional

forms of cold therapy. The CTU as manufactured is excessively cold causing the blood vessels to constrict reducing blood flow.

3.2 As in Plaintiff's case, the reduced blood flow for long periods of time at colder temperatures, relative to traditional forms of cold therapy, causes tissue injury, and in some instances, the tissue's death including injury and/or death of skin, nerve and even bone. In the instances in which the nerve dies, the CTU user often experiences constant, debilitating and chronic pain.

3.3 Plaintiff was injured requiring medical treatment to her left foot ("Underlying Injury"). Thereafter, Plaintiff began receiving treatment of the Underlying Injury from a qualified medical provider.

3.4 On or about June 12, 2009, Plaintiff was prescribed the use of the CTU together with its accessories to be used by Plaintiff as part of the treatment for the Underlying Injury. Defendant designed, developed, manufactured, tested, packaged, promoted, advertised, marketed, distributed, labeled, and/or sold the CTU. On or about June 12, 2009 ("Date of First Use"), Plaintiff began using the CTU.

IV.
CAUSES OF ACTION

COUNT I
NEGLIGENCE

4.1 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.2 Defendant had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertising, supplying, promoting, packaging, sale, and/or

distribution of the CTU, including the duty to assure that the product would not cause users to suffer unreasonable, dangerous personal injuries.

4.3 Defendant failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promoting, advertising, packaging, sale, testing, quality assurance, quality control and distribution of the CTU in interstate commerce because Defendant knew or should have known that using the CTU created a high risk of unreasonable and dangerous personal injuries which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, and any and all further medical complications, such as Plaintiff needs for life-long medical treatment and care, and a fear of developing any further adverse health consequences.

4.4 Defendant's negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and distributing the CTU without thoroughly and adequately testing it;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, designing and distributing the CTU while concealing and suppressing test results;

c. Not conducting sufficient studies and tests to determine whether or not the CTU was safe for its intended use because Defendant knew or should have known that the CTU was indeed unsafe and unfit for use by reason of the dangers to its users;

d. Failing to warn Plaintiff, the medical and healthcare community, including Plaintiff's physician who prescribed the CTU, the general public or the FDA, as soon as Defendant knew or should have known of the dangers of the use of the CTU, such that the prolonged exposure of cold caused by the CTU would result in reduced blood flow and death of tissue reliant on that blood flow;

e. Concealing, suppressing, failing to warn about and/or failing to follow up on the adverse results of clinical testing that occurred, which indeed indicated that the CTU had a high risk of serious and dangerous adverse health effects and consequences;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would foreseeably come into contact with, and more particularly, use the CTU;

g. Advertising and recommending the use of the CTU while suppressing and concealing the known dangers inherent in the use of the CTU;

h. Representing that the CTU was safe for its intended use when it was actually unsafe for its intended purpose, and representing that the CTU had equivalent safety and efficacy to other forms of cold therapy;

i. Suppressing, concealing and omitting information concerning FDA warnings, recommendations, and observations from Plaintiff, Plaintiff's physician who prescribed the CTU, healthcare professionals and the public, while at the same time knowing that the CTU was unsafe, dangerous, and/or nonconforming with FDA regulations; and

j. Suppressing, concealing, omitting, and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of the CTU as compared to other forms of cold therapy.

4.5 Defendant was negligent in the design, research, development, manufacture, promotion, packaging, advertising, distribution, testing, marketing, and sale of the CTU, because Defendant:

a. Failed to use due care in the design, research, manufacture, and development of the CTU so as to avoid the aforementioned risks to individuals when the CTU was used for cold therapy purposes;

b. Failed to design and manufacture the CTU so as to inform the user of the true temperature of the cold to which the user's skin was exposed;

c. Failed to design and manufacture the CTU so as to ensure the proper level of cooling for the proper amount of time for the user's given medical condition;

d. Failed to provide that their product was accompanied by proper and accurate warnings about possible adverse personal injuries associated with the use of the CTU and that the prolonged use of the CTU could and would result in reduced blood flow to the user's tissue and the death of said tissue; and

e. Failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of the CTU.

4.6 Despite the fact that Defendant knew or should have known that the CTU could cause and did cause unreasonably dangerous personal injuries, Defendant

continued and, indeed, still continue to market, manufacture, distribute, advertise, promote and sell the CTU to consumers.

4.7 Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injuries as a result of Defendant' failure to exercise ordinary care, as set forth above.

4.8 Defendant's negligence was the proximate cause of the injuries, harm and economic loss that Plaintiff has suffered and will continue to suffer into the future.

4.9 As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious personal injuries which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, diminished enjoyment of life, decreased energy level, and any and all additional life complications, such as the need for life-long medical treatment, monitoring and the fear of developing further adverse health consequences.

4.10 As a direct and proximate result of the foregoing acts and omissions, Plaintiff required and will require health care and services and has incurred medical, health care, incidental, and related expenses. Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

4.11 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT II
PRODUCTS LIABILITY — DEFECTIVE DESIGN

4.12 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.13 At all times material hereto, Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, or distributed the CTU used by Plaintiff, as described above.

4.14 The CTU was expected to and did reach the intended consumers, handlers and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled and marketed by Defendant.

4.15 At all times relevant, the CTU was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition which was dangerous for use by the public, and, in particular, by Plaintiff.

4.16 The CTU as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the design of the CTU.

4.17 The CTU as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design because when it left the hands of Defendant, it was unreasonably dangerous and also was more dangerous than the ordinary consumer would expect.

4.18 At all times herein mentioned, the CTU was in a defective condition and was unsafe. Defendant knew or should have known that the product was defective and unsafe, especially when the CTU was used in a form and manner instructed and provided by Defendant.

4.19 Defendant knew or should have known, all times material hereto, that the CTU was in a defective condition and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

4.20 At the time of Plaintiff's use of the CTU, the CTU was being used for the purpose and in a manner normally intended, namely for healing through cold therapy.

4.21 Defendant had a duty to create a product that was not unreasonably dangerous for its normal common intended use.

4.22 The CTU as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled and distributed by Defendant was manufactured defectively because the CTU left the hands of Defendant in a defective condition and was unreasonably dangerous for its intended use, for which it was manufactured and sold.

4.23 Defendant designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product that created an unreasonable risk to the health of consumers, and to Plaintiff in particular. Defendant is, therefore, strictly liable for the injuries and damages sustained by Plaintiff.

4.24 Plaintiff could not, by the reasonable exercise of care, have discovered the CTU's defects and perceived its danger.

4.25 The CTU as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled and distributed by Defendant was defective due to inadequate warnings and instructions since Defendant knew or should have known that the CTU created a risk of serious personal injuries, which are permanent and lasting in nature. Defendant failed to adequately test for and warn of these risks.

4.26 The CTU as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled and distributed by Defendant was defective by design because Defendant was aware at the time it was marketed that prolonged use of the CTU could and would result in reduced blood flow to the user's tissue and the death of said tissue.

4.27 The CTU as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, labeled and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because Defendant knew or should have known the risks of serious personal injuries as well as other serious and permanent health consequences from the CTU. Defendant also failed to provide adequate warning for use for consumers of the product, and Defendant continue to improperly advertise, market, label and promote the CTU to the public and the medical community.

4.28 By reason of the foregoing, Defendant is strictly liable in tort to Plaintiff.

4.29 Defendant's defective design of the CTU and its provision of inadequate warnings accompanying the CTU were acts that amount to willful, wanton and/or reckless conduct by Defendant.

4.30 The defects in Defendant's CTU were substantial and contributing factors in causing Plaintiff's injuries.

4.31 As a result of the wrongful acts and omissions of Defendant, Plaintiff was caused to suffer the serious and dangerous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care and an ongoing fear of developing any of additional adverse health consequences.

4.32 As a result of the forgoing acts and omissions, Plaintiff requires and will require more health care services, and did incur medical, health care, incidental and related expenses. Plaintiff is informed and believes she will be required to obtain further medical and/or hospital care, attention, and services.

4.33 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT III
PRODUCTS LIABILITY — FAILURE TO WARN

4.34 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.35 Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released the CTU into the stream of commerce, and in the course of same, directly advertised or

marketed the CTU to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk associated with the use of the CTU.

4.36 The CTU was under the exclusive control of Defendant and was not accompanied by appropriate warnings regarding all possible adverse personal injuries and complications associated with the use of the CTU, nor with adequate warnings regarding the comparative severity, duration and extent of the risk of injuries with such use of the CTU.

4.37 Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of the CTU; no medical care provider would have prescribed — and no consumer would have used — the CTU had those facts been made known to such providers and consumers.

4.38 Defendant failed to perform or otherwise facilitate adequate testing. Such testing would have shown that the CTU posed serious personal injuries and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA, and the public, including Plaintiff.

4.39 The CTU, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant and/or each of them, was defective due to inadequate post-marketing warnings and/or instructions because, after Defendant knew or should have known of the risk of serious personal injuries and complications from the use of the CTU, Defendant failed to provide adequate warnings

to medical care providers, the FDA, and the consuming public, including Plaintiff, and continued to promote the CTU aggressively.

4.40 As a direct and proximate result of the conduct of Defendant as detailed above, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

4.41 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

4.42 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.43 Defendant expressly warranted that the CTU was safe and fit for use by consumers, that it was of merchantable quality, that it did not produce dangerous personal injuries and that it was adequately tested and fit for its intended use.

4.44 At the time of making such express warranties, Defendant knew or should have known that the CTU does not conform to these express representations because the CTU is not safe and has numerous serious risks of personal injury, many of which Defendant did not accurately warn about.

4.45 As a foreseeable, direct and proximate result of the breach of these warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm, emotional injuries and economic loss.

4.46 Plaintiff did rely on the express warranties of Defendant with respect to the CTU.

4.47 Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendant in connection with the use recommendation, description and/or dispensing of the CTU.

4.48 Defendant breached the aforesaid express warranties because the CTU was and is defective and unreasonably unsafe for its intended purpose.

4.49 Defendant expressly represented to Plaintiff, Plaintiff's physicians and healthcare providers that the CTU was safe and fit for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous personal injuries in excess of those risks associated with traditional methods of cold therapy, that the personal injuries it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

4.50 Defendant knew or should have known its representations and warranties were false, misleading and untrue because the CTU was not safe and fit for its intended use, and the CTU caused its users serious injuries that were not adequately identified and represented by Defendant.

4.51 As a result of the foregoing acts and/or omissions, Plaintiff was caused to suffer serious and grievous personal injuries, including, but not limited to, physical pain

and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and monitoring, and a perpetual fear of developing any of additional adverse health consequences.

4.52 As a foreseeable, direct and proximate result of the foregoing acts and omissions, Plaintiff required and will require health treatment and care, and did incur medical, health care, incidental and related expenses, and losses. Plaintiff is informed and believes she will be required to have further medical and/or hospital care, attention, and services.

4.53 **WHEREFORE,** the Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT V
BREACH OF IMPLIED WARRANTIES

4.54 Plaintiff repeats and re-alleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.55 At all times relevant, Defendant manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the CTU.

4.56 At the time Defendant marketed, sold and distributed the CTU for use by Plaintiff, Defendant knew of the intended use of the CTU and impliedly warranted the product to be of merchantable quality, and safe and fit for such intended use.

4.57 Defendant impliedly represented and warranted to the users of the CTU and their physicians, healthcare providers, the general public, Plaintiff and the FDA that the CTU was safe and of merchantable quality and fit for the ordinary purpose for which the product was to be used.

4.58 Defendant's representations and warranties were false, misleading and inaccurate because the CTU was unsafe, unreasonably dangerous, not of merchantable quality and otherwise defective.

4.59 Plaintiff, Plaintiff's physician(s) and members of the medical community relied on the superior skill and judgment of Defendant as to whether the CTU was of merchantable quality and safe and fit for its intended use, and they also relied on the implied warranty of merchantability of fitness for this particular use and purpose.

4.60 The CTU was put into the stream of commerce by Defendant in a defective, unsafe and inherently dangerous condition, and the products and materials were expected to and did reach Plaintiff without substantial change in the condition in which the CTU was sold.

4.61 Defendant breached their implied warranty because the CTU was not fit for its intended use and purpose.

4.62 As a direct and proximate result of Defendant's acts and omissions, Plaintiff was caused to suffer serious and dangerous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for

life-long medical treatment and care, and a perpetual fear of developing any of additional adverse health consequences.

4.63 As a foreseeable, direct and proximate result of Defendant's acts and omissions, Plaintiff required and will continue to require healthcare and services, and did incur medical, health care, incidental and related expenses. Plaintiff is informed and believes and alleges he will need additional medical and/or hospital care, attention, and services in the future.

4.64 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT VI
COMMON LAW FRAUD

4.65 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.66 Defendant falsely and fraudulently represented to the medical and healthcare community, Plaintiff, the FDA and the public that the CTU had been tested and was found to be safe and effective for cold therapy.

4.67 When Defendant made its representations, Defendant knew or should have known that those representations were false and Defendant willfully, wantonly and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the CTU, such as Plaintiff.

4.68 These representations were made by Defendant with the intent of defrauding and deceiving the medical community, Plaintiff and the public, and also inducing the medical community, Plaintiff and the public, to recommend, prescribe, dispense, and purchase the CTU for use as a means of cold therapy, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety and welfare of Plaintiff.

4.69 In making the representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendant fraudulently concealed and intentionally omitted the following material information:

a. That the CTU was not as safe as other forms of cold therapy;

b. That prolonged use of the CTU could and would result in reduced blood flow to the user's tissue resulting in the death of said tissue;

c. That the risk of adverse effects with the CTU were higher than those with other forms of cold therapy;

d. That the risk of adverse effects with the CTU was not adequately tested and known by Defendant;

e. That the limited clinical testing revealed that the CTU had a higher risk of adverse effects, in addition to and above and beyond those associated with traditional forms of cold therapy;

f. That Defendant deliberately failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. That Defendant was aware of dangers in the CTU's design, in addition to and above and beyond those associated with traditional cold therapy methods;

h. That the CTU was defective, and that it caused dangerous and adverse personal injuries as well as other severe and permanent health consequences at a much more significant rate than traditional forms of cold therapy;

i. That patients needed to be monitored more regularly than usual while using the CTU;

j. That the CTU was manufactured defectively; and

k. That the CTU was designed negligently, and designed defectively.

4.70 Defendant was under a duty to disclose to Plaintiff and Plaintiff's physicians the defective nature of the CTU, including, but not limited to the heightened risks of personal injuries.

4.71 Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous personal injuries and hence, cause dangerous injuries and damage to persons who used the CTU, including Plaintiff.

4.72 Defendant's concealment and omissions of material fact concerning the safety of the CTU were made purposefully, willfully, wantonly and/or recklessly to mislead, to cause Plaintiff's physicians and healthcare providers to purchase, prescribe and/or dispense the CTU and/or to mislead Plaintiff into reliance and cause Plaintiff to use the CTU.

4.73 At the time these representations were made by Defendant and at the time Plaintiff used the CTU, Plaintiff was unaware of the falsehood of these representations and reasonably believed them to be true.

4.74 Defendant knew and had reason to know that the CTU could and would cause severe and grievous personal injury to the users of the CTU and that it was inherently dangerous in a manner that exceeded any purported, inaccurate or otherwise downplayed warnings.

4.75 In reliance upon these false representations, Plaintiff was induced to, and did use the CTU, thereby sustaining severe and permanent personal injuries and damages. Defendant knew or had reason to know that Plaintiff and Plaintiff's physicians and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions and that these included material omissions of facts surrounding the use of the CTU, as described in detail herein.

4.76 Plaintiff reasonably relied on revealed facts which negligently, foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in use of the CTU.

4.77 As a result of Defendant's research and testing or lack thereof, Defendant blatantly and intentionally distributed false information, including, but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians that the CTU was safe for use as a means of providing cold therapy. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff and the public at large.

4.78 Defendant had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers and the FDA.

4.79 The information distributed to the public, the medical community, the FDA and Plaintiff by Defendant included, but was not limited to reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations which were false and misleading and contained omissions and concealment of the truth about the dangers of the use of the CTU.

4.80 Defendant intentionally made material misrepresentations to the medical community and public, including Plaintiff regarding the safety of the CTU, specifically that the CTU did not have dangerous and/or serious adverse health safety concerns. Defendant intentionally made material representations to Plaintiff, the public and the medical community regarding the safety of the CTU, specifically that the CTU was as safe as other means of cold therapy.

4.81 Defendant's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community and Plaintiff; to falsely assure them of the quality and fitness for use of the CTU; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase and continued to use the CTU.

4.82 Defendant made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the CTU did not present serious health risks.

4.83 These representations, and others made by Defendant, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

4.84 These representations, and others made by Defendant, were made with the intention of deceiving and defrauding Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community and were made in order to induce Plaintiff and Plaintiff's respective healthcare professionals to rely on misrepresentations and caused Plaintiff and other CTU users to purchase, rely, use and request the CTU and their healthcare professionals to dispense, recommend or prescribe the CTU.

4.85 Defendant recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the CTU to the public at large, and Plaintiff in particular, for the purpose of influencing the sales of a product known to be dangerous and defective and/or not as safe as other alternatives, including traditional forms of cold therapy such as bags of ice.

4.86 Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations for the purpose of deceiving and lulling Plaintiff, as well as Plaintiff's healthcare professionals, into a false sense of security so Plaintiff and Plaintiff's healthcare providers would rely on Defendant' representations, and Plaintiff would request and purchase the CTU and Plaintiff's healthcare providers would dispense, prescribe and recommend the CTU.

4.87 Defendant utilized "direct-to-consumer" advertising to market, promote and advertise the CTU.

4.88 At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the CTU. Plaintiff did not discover the false representations of Defendant, nor would Plaintiff, with reasonable diligence, have discovered the true facts or Defendant's misrepresentations.

4.89 Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the CTU, Plaintiff would not have purchased, used or relied on the CTU.

4.90 Defendant's wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly and/or purposefully on Plaintiff.

4.91 As a foreseeable, direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer the serious and dangerous personal injuries, including, but not limited to physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications such as Plaintiff's need for life-long medical treatment and care, and a perpetual fear of developing any of additional adverse health consequences.

4.92 As a foreseeable, direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff required and will continue to require health care and services and has incurred medical, health care, incidental and related expenses. Plaintiff is

informed and believes he will be required to obtain further medical and/or hospital care, attention and services in the future.

4.93 As a foreseeable, direct and proximate result of Defendant's willful and wanton misconduct and reckless disregard for Plaintiff's well being, Plaintiff is entitled to punitive or exemplary damages as well as compensatory damages.

4.94 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

4.95 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.96 Defendant had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public that the CTU had been tested and found to be safe and effective for cold therapy. The representations made by Defendant, in fact, were false. Plaintiff relied on representations supplied by Defendant to the physician to assess the risks and potential damages that might be associated with using the CTU.

4.97 Defendant failed to exercise ordinary care in the representations concerning the CTU while they were involved in its manufacture, sale, testing, quality assurance, quality control and distribution in interstate commerce because Defendant

negligently misrepresented the CTU's high risk of unreasonable, dangerous and adverse personal injuries.

4.98 Defendant breached its duty in representing the CTU poses no serious risk of personal injury to Plaintiff, Plaintiff's physicians and the medical and healthcare community.

4.99 As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant as set forth herein, Defendant knew and had reason to know that the CTU had been insufficiently tested or had not been tested at all and that it lacked adequate and accurate warnings and that it created a high risk and/or higher than acceptable risk and/or higher than reported and represented risk of personal injuries, which are permanent and lasting in nature.

4.100 As a foreseeable, direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff required and will continue to require health care and services and has incurred medical, health care, incidental and related expenses. Plaintiff is informed and believes he will be required to obtain further medical and/or hospital care, attention and services in the future.

4.101 **WHEREFORE,** Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

COUNT VIII
PUNITIVE DAMAGES

4.102 Plaintiff repeats and realleges each and every allegation of this Complaint contained herein as if each were set forth fully and completely and with the same force and effect as if more fully set forth herein.

4.103 Plaintiff is entitled to punitive damages because Defendant's failure to warn was reckless and without regard for public safety and welfare. Defendant misled both the medical community and the general public, including Plaintiff, by making false representations about the safety of the CTU. Defendant downplayed, understated and/or disregarded their knowledge of the serious and permanent personal injuries associated with the use of the CTU despite available information demonstrating that the CTU was likely to cause serious personal injuries to its users.

4.104 Defendant was or should have been in possession of evidence demonstrating that the CTU caused serious personal injuries. Nevertheless, Defendant continued to market the CTU by providing false and misleading information with regard to its safety and efficacy.

4.105 Defendant failed to provide warnings that would have dissuaded physicians from prescribing the CTU and consumers from purchasing and using the CTU thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming or using the CTU.

4.106 **WHEREFORE,** Plaintiff demands judgment against Defendant and each of them, individually, jointly and severally and requests compensatory, treble and punitive

damages, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

V.
COMPENSATORY DAMAGES

5.1 Plaintiff has suffered:

a. pain, suffering, and inconvenience;

b. pain, suffering, and inconvenience that in reasonable probability will be sustained in the future;

c. emotional distress;

d. emotional distress that in reasonable probability will be sustained in the future;

e. hospital and medical expenses;

f. future hospital and medical expenses;

g. disfigurement;

h. disfigurement that in reasonable probability will be sustained in the future;

i. physical impairment;

j. physical impairment that in reasonable probability will be sustained in the future;

k. loss of consortium;

l. loss of earnings; and/or

m. loss of future earning capacity.

VI.
JURY DEMAND

6.1 Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff requests a trial by jury on all issues in this case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a. Compensatory damages to Plaintiff for past and future damages, including, but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, healthcare costs, and care together with interest and costs as provided by law;

b. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless and indifferent acts of Defendant which demonstrated a complete disregard and reckless indifference for the safety and welfare of the public and of Plaintiff in an amount sufficient to punish Defendant and deter future conduct, together with interest, according to proof;

c. Reasonable attorneys fees;

d. The costs of these proceedings; and,

e. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

WATTS GUERRA CRAFT, LLP

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